REVIEW MANAGEMENT

Accepting Electronic Case Report Forms and Case Report Tabulations

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PURPOSE To establish policies and procedures by which the Center for Drug Evaluation and Research (CDER) will grant a waiver for electronic case report forms (CRFs) and case report tabulations (CRTs) that are not accompanied by paper counterparts. Waivers are required until proposed 21 CFR Part 11 on electronic records and signatures is published in final form and takes effect.

BACKGROUND

The Agency has published proposed regulations (59 FR 45160, August 31, 1994) which would, under certain circumstances, allow the FDA to accept electronic submissions without the accompaniment of a paper copy. This MAPP outlines the procedures for handling electronic CRFs and CRTs within the Center until the final rules are published and effective.

REFERENCES

- Federal Register, Wednesday, August 31, 1994, Vol. 59, No. 168, page 45160.

- 21 CFR 314.50(f)
- 21 CFR 314.90

DEFINITIONS

Sponsor. The holder of the drug application.

POLICY

- Electronic submissions of CRFs and CRTs without paper counterparts, including archival paper copies, will be accepted by the Center for Drug Evaluation and Research on a case-by-case basis.
- A waiver of the requirements for the submission of paper CRFs and CRTs may be granted by the Center Director if the reviewing division recommends it and the sponsor specifically states in its request that the electronic submission was prepared in a manner that is substantially consistent with the requirements in the FDA's proposed rules regarding electronic signatures and electronic records (proposed Part 11) and that paper copies of the CRFs and CRTs will be maintained as required under 21 CFR 312.57(b).
- An electronic-only submission of CRFs and CRTs should conform to CDER's archiving policy for electronic submissions.
- If the electronic submission is incomplete or unacceptable, the waiver is not binding and CDER may request the usual hard copy submission.

RESPONSIBILITIES AND PROCEDURES

- Inquiries from sponsors concerning submission of electronic-only copies of CRFs and CRTs should be referred to the Project Manager (PM)/Consumer Safety Officer (CSO) in the appropriate reviewing division.
- **The PM/CSO is responsible for:**

  1. requesting that the sponsor submit its request in writing to the review division;

  2. directing the sponsor to clearly state the following in the written request:

The electronic case report forms and case report tabulations have been prepared in a manner that is substantially consistent with the FDA's proposed rules regarding electronic signatures and electronic records, proposed 21 CFR Part 11, 59 FR 45160 (August 31, 1994). Paper copies of the CRFs and CRTs will be maintained as required under 21 CFR 312.57(b).

3. advising the sponsor that the submission should be consistent with the standards in proposed 21 CFR Part 11;

4. evaluating the request with affected review division personnel to determine whether the division agrees with the sponsor's proposed submission of electronic-only CRFs and CRTs. The division will determine whether or not the proposed electronic submission meets division needs;

5. preparing a letter informing the sponsor that the waiver is granted (see Attachment A) or denied. The letter should be prepared for the Center Director's signature;

6. forwarding the letter to the Associate Director for Policy for concurrence after appropriate Division and Office concurrences have been received; and,

7. directing the sponsor to contact the Division of Information Systems Design (DISD) to discuss CDER's electronic archiving policy.

- **DISD is responsible for:**

  1. ensuring that electronic CRF and CRT submissions are consistent with CDER's electronic archiving policy; and,

  2. maintaining a tracking database and a repository of electronic submissions.

- **The Associate Director for Policy is responsible for:**

  1. reviewing the waiver letter for consistency and compliance with this policy;

  2. forwarding the letter to the Center Director; and,

3. maintaining a file of letters granting and denying waiver requests.

- **The Center Director is responsible for:**

  signing the letter granting the waiver and returning it to the initiating division for issuance.

EFFECTIVE DATE

This guide is effective upon date of publication.

Attachment A

SAMPLE LETTER FOR GRANTING A WAIVER

Dear _____:

Please refer to your [investigational] new drug application submitted pursuant to section 505(b) [505(i) or 507] of the Federal Food, Drug, and Cosmetic Act for [product name].

Reference is also made to your letter of [date], requesting a waiver of the requirements for the submission of paper case report forms and/or case report tabulations in conjunction with the forthcoming [product name] application.

You have represented in your letter that the electronic case report forms and case report tabulations have been prepared in a manner that is substantially consistent with the FDA's proposed rules regarding electronic signatures and electronic records, proposed 21 CFR Part 11, 59 FR 45160 (August 31, 1994).

We have concluded that under 21 CFR 314.90(b)(2), your alternative electronic submission justifies a waiver of the "hard copy" requirements of 21 CFR 314.50(f). Consequently, your waiver request is granted.

Should future retrieval be deemed necessary, and as a condition of granting this waiver, you are required to maintain paper copies of the case report forms and tabulations as required under 21 CFR 312.57(b).

If you have any further questions, please contact _____, Project Manager [or Consumer Safety Officer], at [telephone number].

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research